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10/820,492

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EXAMINER

SAIDI, AZADEH

ART UNIT

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3709

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/820,492

**Applicant(s)**

BAYER ET AL.

**Examiner**

Anita Saidi

**Art Unit**

3709

**– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "32" and "46" have both been used to designate Bottom surface. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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3. Claims 1,4-6, 8,10,12 & 17,19 & 23, 26-28, 32 & 36-42,44 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 6,468,222 to Mault et al (Mault).

In ref to claims 1 & 12 & 23 & 36:

A symmetrical breath-testing device housing, comprising:

A base to be gripped by an operator (12); a display (18) oriented to be aligned with an operator's direct line of view while gripping said base; and a mouthpiece interface (20 in Fig. 8) for interfacing with a removable mouthpiece (Col. 4, lines 6-31), said mouthpiece interface comprising a body comprising at least one substantially planar surface (Fig. 8) and it is oriented with respect to said base such that when a subject blows into the mouthpiece, said display is not in the direct line of view of the subject (Fig. 8).

In ref to claims 4 & 26:

A housing comprises a first sidewall (the front side of body 12) and an opposite second sidewall (the back side of body 12) coupled together at a front edge and a back edge, said first and second sidewalls extending radially between a top surface and a bottom surface, said display located along said front edge, said mouthpiece interface located along said top surface (Fig. 2)

In ref to claims 5 & 27:

The mouthpiece interface is oriented with respect to said housing such that when a mouthpiece is coupled thereto, the mouthpiece extends outward from said back edge (Fig. 8).

In ref to claim 37:

The housing further comprises a mouthpiece interface sized to receive said mouthpiece in sealing contact therein. (15 & Col. 28, lines 9-20 & Figs. 21-22)

In ref to claims 6 & 28 & 40:

The mouthpiece interface is further oriented such that when a mouthpiece is coupled thereto, the mouthpiece extends at least one of obliquely from said top surface and substantially parallel to said top surface (Fig. 8).

In ref to claims 8, 10 & 32, 38-39:

A light source for illuminating a portion of interface, and an opening for light to pass from an interior of said housing to an exterior of said housing for illuminating at least a portion of said interface (Col. 3, lines 59- 67 & Col. 4, lines 1-5)

In ref to claim 17:

The mouthpiece body comprising a substantially planar surface (20 in Fig. 8).

In ref to claim 19:

The body further comprises at least one port for channeling air there through into the breath-testing device (Fig. 8).

In ref to claim 41:

The mouthpiece is further oriented with respect to said housing such that discard breath discharged from said housing is not directed at the operator (72 in fig. 4).

In ref to claim 42:

The mouthpiece comprises at least one of a tube and a funnel (Fig. 2).

In ref to claim 44:

At least a portion of said mouthpiece has a cross-sectional shape that is substantially similar to at least portion a cross-sectional shape defined by said mouthpiece interface, such that said mouthpiece interface facilitates positioning said mouthpiece in proper alignment with respect to said housing (Fig. 8 & Figs. 21-22).

4. Claims 1, 9, 23 & 29 & 31 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 4,656,008 to Gump (Gump).

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In ref to claims 1 & 23:

A symmetrical breath-testing device housing, comprising:

A base to be gripped by an operator (42); a display (68) oriented to be aligned with an operator's direct line of view while gripping said base; and a mouthpiece interface (48, 44 & 46) for interfacing with a removable mouthpiece (46), said mouthpiece interface comprising a body comprising at least one substantially planar surface (ring around the mouthpiece 46) and it is oriented with respect to said base such that when a subject blows into the mouthpiece, said display is not in the direct line of view of the subject (Fig. 8).

In ref to claims 9 & 29:

The mouthpiece is further oriented with respect to said housing such that discard breath discharged from said housing is not directed at the operator (58 in Fig. 8).

In ref to claim 31:

At least one actuator for controlling illumination of at least a portion of said housing (Col. 5, lines 23- 31).

5. Claims 13, 15-16 & 54-55 & 57-58, 60 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 4,274,425 to Lutz et al (Lutz).

In ref to claims 13 & 54 & 57:

The mouthpiece comprising a body (5) comprising a first end (38), a second end (the end towards 27), said first end being open so that a subject can blow air into said mouthpiece, said second end being closed (Fig. 1), said mouthpiece further comprising at least one port for channeling air blown into said mouthpiece into the breath testing device (15).

In ref to claim 15:

The mouthpiece snaps into engagement with the breath-testing device (Snap members 23 & 25 & 33 & 35 & Col. 3, lines 40-53).

In ref to claim 16:

A stop (the bend at 41) extending radially outward from said body to facilitate positioning a subject's mouth during breath testing (Fig. 1).

In ref to claim 55:

The body further comprises at least one port for channeling air there through into the breath-testing device (Fig. 1).

In ref to claims 58 & 60:

One of said first or second body portion is rounded or semi-circular to facilitate engagement with the breath-testing device (Fig. 1).



***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 2,7,11 & 24,30,33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,468,222 to Mault et al (Mault) in view of US Pat. No. 5,291,898 to Wolf (Wolf).

In ref to claims 2,7,11 & 24,30,33:

Mault teaches all the limitations of claims 1 & 23 see rejection above.

However, Mault does not teach:

A mouthpiece ejector for facilitating removal of a mouthpiece from said housing.

At least one actuator for controlling operation of the breath-testing device.

Wolf teaches a hand held device for measuring breath alcohol. Wolf discloses that the device includes an ejector (120) for ejecting the mouthpiece forceably, so that the mouthpiece is ejected into a refuse container or onto the ground without the need of the officer administering the test to touch the used mouthpiece (Col. 9, lines 9-17). Wolf also teaches the use of an actuator for ejecting the mouthpiece.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to have added the ejector and actuator of Wolf to the system of Mault in order to prevent the operator to touch the used mouthpiece, as it has been explicitly thought by Wolf.

8. Claims 14 & 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 4,274,425 to Lutz et al (Lutz) in view of US Pat. No. 5,291,898 to Wolf (Wolf).

In ref to claims 14 & 56:

Lutz teaches all the limitations of claims 13 & 54, see the rejection above.

However, Lutz does not teach that:

The mouthpiece further comprises a discard breath outlet oriented such that discard breath is not directed at an operator of the breath-testing device during testing.

Wolf teaches a hand held device for measuring the breath alcohol. Wolf teaches that the mouthpiece comprises a discard breath outlet (exhaust 26 & port 11, presented as 13 in Fig. 2) oriented such that discard breath is not directed at an operator of the breath-testing device during testing (Fig. 2).

Therefor it would have been obvious to one having ordinary skill in the art at the time the invention was made to have added the hand held device of Wolf to the mouthpiece of Lutz, in order to measure and display the breath alcohol.

9. Claims 18 & 34 & 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,468,222 to Mault et al (Mault) in view of US Pat. No. 4,202,353 to Hirsch et al (Hirsch).

In ref to claims 18 & 34 & 45:

Mault teaches all the limitations of claims 17 & 23 & 36, see the rejection above.

However, Mault does not teach that:

The mouthpiece has a selected cross-sectional shape, said selected cross-sectional shape being one of: a D-shaped cross-sectional shape and a V-shaped cross-sectional shape.

Hirsch teaches:

A temperature and respiration-sensing device, with a mouthpiece (12), that has a different design the conventional mouthpieces used for breath testing. However, matters relating to ornamentation only which have no mechanical function cannot be relied upon to

patentably distinguish the claimed invention from the prior art. See  
MPEP § 2144.01.

Therefore it would have been obvious to one having ordinary skill in the art  
at the time the invention was made to have used a different design for the  
mouthpiece.

10. Claim 59 rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat.  
No. 4,274,425 to Lutz et al (Lutz) in view of US Pat. No. 4,202,353 to Hirsch et al  
(Hirsch).

In ref to claim 59:

Lutz teaches all the limitations of claim 54, see the rejections above.

However, it does not teach that:

The mouthpiece has a selected cross-sectional shape, said  
selected cross-sectional shape being one of: a D-shaped cross-  
sectional shape and a V-shaped cross-sectional shape.

Hirsch teaches:

A temperature and respiration-sensing device, with a mouthpiece  
(12), that has a different design the conventional mouthpieces used  
for breath testing. However, matters relating to ornamentation only  
which have no mechanical function cannot be relied upon to

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patentably distinguish the claimed invention from the prior art. See MPEP § 2144.01.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to have used a different design for the mouthpiece.

11. Claim 47-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 4,202,353 to Hirsch et al (Hirsch).

In ref to claim 47:

Hirsch teaches:

A temperature and respiration-sensing device, with a mouthpiece (12), that has a different design the conventional mouthpieces used for breath testing.

However, it does not teach:

The mouthpiece has a selected cross-sectional shape, said selected cross-sectional shape being one of: a D-shaped cross-sectional shape and a V-shaped cross-sectional shape.

Matters relating to ornamentation only, which have no mechanical function, cannot be relied upon to patentably

distinguish the claimed invention from the prior art. See

MPEP § 2144.01.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to have used a different design for the mouthpiece.

In ref to claim 50:

The mouthpiece further comprises a discard breath outlet (26) oriented such that discard breath is not directed at an operator of the breath-testing device during testing.

In ref to claim 51:

The mouthpiece body comprising a substantially planar surface (Fig. 2).

In ref to claims 48 & 49 & 52:

The body further comprises an external surface, an internal surface (Fig. 2, upper and lower side of 12), and at least one inlet port and one outlet port extending there between, said inlet port (20 & 24) for channeling air from the passageway into the breath testing device and said outlet port (26) for channeling discard breath air from the mouthpiece during testing.

In ref to claim 53:

One of said first or second body portion is rounded to facilitate engagement with the breath-testing device (Fig. 2).

12. Claims 3 & 25 & 43 rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,468,222 to Mault et al ('222) in view of US Pat. No. 6,402,698 to Mault ('698).

In ref to claims 3 & 25 & 43:

'222 teach all the limitations of claims, 1 & 23 & 36, see the rejections above.

However, it does not teach:

A manual sample button located on an edge of said base that is opposite an edge where said display is located, such that when an operator stands with the subject and said display in the operator's direct field of view, the operator may at any time press said manual sample button without compromising the operator's grip on said base.

'698 teaches:

A device for measuring metabolic calorie; by employing respiratory gas analysis. It also teaches that the system is operable either automatically or manually (Col. 5, lines 60-67), by choosing one of

the push buttons (80), in order to give the user the option of manual or automatic operation.

However, the push buttons of '698 are placed under the display not on an edge opposite to the display. The location of the manual push button does not add any advantage to the operator. The operator is still capable to keep the subject in his direct line of view and without compromising that he can easily perform the activation of the system, either manually or automatically. The particular placement of the manual button is an obvious matter of design choice See § 2144.01 for more information.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to have Modified the system of '222 in order to have a manual button of '698 in order to give the operator more control on the device.

13. Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,468,222 to Mault et al (Mault) in view of US Pat. No. 6,026,674 to Gammenthaler (Gammenthaler).

In ref to claims 20 & 21 & 22:

Mault teaches all the limitation of claim 17, see the above rejection.

However, Mault does not teach:



The body further comprises at least a plurality of ports for channeling airflow into the breath-testing device for sampling, with at least one pressure sensor and a thermistor.

Gammenthalerm, teaches an apparatus for determining a person's sobriety, comprising a mouthpiece consisting of multiple port for channeling airflow into the breath-testing device, including a temperature sensor and a pressure sensor (Fig. 1 & Col. 2, lines 46-63).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to have incorporated the pressure sensor and a temperature sensor of Gammenthaler in the system of Mault in order to monitor the physiological change as well as exhalation performance of the patient .

14. Claims 35 & 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,468,222 to Mault et al (Mault) in view of US Pat. No. 4,274,425 to Lutz et al (Lutz).

In ref to claims 35 & 46:

Mault teaches all the limitations of claims 23 & 36, see the rejections above.

However, Mault does not teach that:

The first end of mouthpiece body is closed and an opposed second end of body is open to enable a subject being tested to blow air into body, body further comprising at least one port so that air blown into body can pass through port.

Lutz teaches a mouthpiece for gas measurement. Lutz discloses a mouthpiece having the first end of mouthpiece closed and an opposed second end is open to enable a subject being tested to blow air into body, body further comprising at least one port so that air blown into body can pass through port (Fig. 1), in order to direct the airflow in two chambers (15 & 17) instead of one, as it has been disclosed by Mault. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified and added the mouthpiece of Lutz to that of the Mault in order to direct the airflow in two chambers instead of one, in order to perform different test on the exhaled breath.

### ***Double Patenting***

15. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states, "Whoever invents or discovers any new and useful process ... may obtain a patent therefor..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

16. Claims 1-5 & 9 & 12-27 & 29 & 34-37 & 41 & 43 & 45-60 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-29 of copending Application No. 11/089,655. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

### ***Conclusion***

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Pat. Pub. No. 2005/0009195 to Wang has been included because it discloses a Device for analyzing the alcohol content of respiratory gas. US pat. No. 6,150,177 to Stock has been included because it discloses a device for determining the temperature of the gas sample during breath alcohol measurement. US pat. No. 4,649,027 to Talbot also discloses a breath tester. US Pat. No. 4,902,628 to Blair has been disclosed because it also discloses an apparatus for detecting sobriety of a person.


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18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anita Saidi whose telephone number is 571-270-3001. The examiner can normally be reached on Monday-Thursday 8:30 am - 7:00 pm Est..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kenneth Bomberg can be reached on 571-272-4922. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AS 6/8/2007



THAO X. LE  
PRIMARY PATENT EXAMINER